Health Canada Santé Canada

Your health and safety... our priority. *Votre santé et votre sécurité... notre priorité.*

Health Product InfoWatch

June 2018

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REPORTING ADVERSE REACTIONS

Canada Vigilance Program
Online: Adverse Reaction and Medical Device Problem Reporting
Telephone: 1-866-234-2345
Fax or mail: Form available online

SUBSCRIBE

To receive the Health Product InfoWatch and notifications of health product advisories electronically, subscribe to MedEffect™ e-Notice **or to** MedEffect™ Canada RSS feeds.

HEALTH PRODUCTS MENTIONED IN THIS ISSUE

Pharmaceuticals and Biologics

Erfa-Tranexamic 100 mg/mL
Gadolinium-based contrast agents
GlaxoSmithKline Inc. vaccines
Isoniazid
Lynparza (olaparib)
Pradaxa (dabigatran etexilate)
Propecia (finasteride)
Proscar (finasteride)

Medical Devices

Barbed sutures
Enterra Therapy System

Other

Unauthorized health products

This monthly publication is intended primarily for healthcare professionals and includes information on pharmaceuticals, biologics, medical devices and natural health products. It provides a summary of key health product safety information published in the previous month by Health Canada, as well as a selection of new health product safety information meant to raise awareness. New information contained in this issue is not comprehensive but rather represents a selection of clinically relevant items warranting enhanced dissemination.

Canada

ANNOUNCEMENT

Opioid marketing and advertising consultation

Recognizing that the over-prescription of opioids has contributed to Canada's opioid crisis, the Government of Canada is taking action to address industry's opioid marketing practices.

A public consultation on the intent to restrict opioid advertising is open from June 19, 2018 to July 18, 2018. Specifically, stakeholders and the public are invited to share information and views on the benefits and risks of opioid advertising and potential restrictions.

For more information and to share your views, read the Notice of Intent to restrict the marketing and advertising of opioids.

MONTHLY RECAP OF HEALTH PRODUCT SAFETY INFORMATION

The following is a list of** health product advisories, type I recalls **as well as** summaries of completed safety reviews **published in May 2018 by Health Canada.

Barbed sutures Health Professional Risk Communication	Health Canada is aware of international reports of small bowel obstruction (SBO) associated with the use of barbed (knotless) suture devices used in various abdominal or pelvic surgeries. The barbed suture can hook onto the small intestine and potentially cause a post-operative blockage. Healthcare professionals are advised to consider barbed sutures as a possible explanation in surgical cases showing post-operative signs/symptoms of SBO when these devices have been used during closure. Health Canada is working with relevant medical device manufacturers to update the labelling for barbed suture devices to include this safety information.
Enterra Therapy System Summary Safety Review	This safety review evaluated the potential lack of effectiveness associated with the use of Enterra Therapy System. Health Canada's review of the available information concluded that certain patients with gastroparesis who are candidates for treatment with Enterra may not benefit from the use of this device. This risk of potential lack of effectiveness is described in the medical literature and is labelled in the device's Instructions for Use. Health Canada will continue to monitor the safety information involving Enterra.

Erfa-Tranexamic 100 mg/ mL (5 mL) Drug Recall	ERFA Canada 2012 Inc. recalled Erfa-Tranexamic 100 mg/mL (5 mL) due to the presence of particles in the affected lots (P322A, P321A, P347A, P348A, P349A).
Gadolinium-based contrast agents Summary Safety Review	This safety review evaluated the risk of gadolinium deposition in the brain and potential neurological adverse reactions associated with the use of gadolinium-based contrast agents (GBCAs): Dotarem (gadoterate meglumine), Gadovist (gadobutrol), Magnevist (gadopentetate d[illegible]umine), MultiHance (gadobenate dimeglumine), Omniscan (gadodiamide), Optimark (gadoversetamide), Primovist (gadoxetate disodium) and ProHance (gadoteridol). Health Canada's review found a link between repeated GBCA administration and the risk of gadolinium deposition in the brain. This risk was considered to be potentially greater in children, pregnant women, and in people receiving multiple doses. At the time of the review, no neurological adverse reactions were linked to gadolinium deposition in the brain. Health Canada is working with the manufacturers to make changes to the Canadian product monographs to include additional warnings.
GlaxoSmithKline Inc. vaccines Health Professional Risk Communication	Leakages have occurred from ceramic coated tip (CCT) syringes used for several GlaxoSmithKline Inc. vaccines (Boostrix, Boostrix-Polio, Engerix-B, Havrix, Havrix Junior, Infanrix-IPV, Infanrix-IPV/HIB, Infanrix-hexa, Twinrix and Twinrix Junior). The leakages occurred during vaccine preparation or administration. Administration of vaccines from leaking syringes can result in a potential risk of underdosing. Healthcare professionals are advised not to use the syringe when the leakage occurs during reconstitution. When the leakage occurs during vaccine injection and the individual received less than the standard dose, the decision to revaccinate should take into account both the potential benefits and risks associated with administering a repeated dose. The introduction of improved CCT syringes on the Canadian market is anticipated in 2018. However, both improved and affected CCT syringes are expected to be on the market until the end of 2019.
Isoniazid Summary Safety Review	This safety review evaluated the risk of pancreatitis associated with isoniazid. Health Canada's review concluded that there is a rare potential risk of pancreatitis with the use of isoniazid. Health Canada is working with the manufacturer to update the Canadian product monograph for isoniazid products to inform about this risk.

Pradaxa (dabigatran etexilate) Summary Safety Review	This safety review evaluated the risk of liver injury associated with Pradaxa. Health Canada's review concluded that there may be a link. Health Canada will be working with the manufacturer to update the Canadian product monograph for Pradaxa to inform healthcare professionals and patients about this risk.
Unauthorized health products "Sāj" kratom products Unauthorized Botox and other health products Unauthorized prescription antibiotic drugs Update - Multiple unauthorized products	Health Canada advised Canadians about various unauthorized health products being sold at retail locations across Canada or online that may pose serious health risks.

NEW HEALTH PRODUCT SAFETY INFORMATION

The following topics have been selected to raise awareness and, in some cases, to stimulate reporting of similar adverse reactions.

PRODUCT MONOGRAPH UPDATES

The following safety labelling updates, which were recently made to the Canadian product monograph, have been selected for your awareness. A complete list of safety labelling updates is available on Health Canada's *Product Monograph Brand Safety Updates*. ***Canadian product monographs can be accessed through Health Canada's*** *Drug Product Database*.

Proscar and Propecia (finasteride)

New information regarding the risk of **muscle-related disorders** has been added to the *Post-Market Adverse Drug Reactions* and *Consumer Information* sections of the Canadian product monographs for Proscar and Propecia.

Key messages for healthcare professionals:[1,2]

- Rare cases of muscle-related disorders, such as rhabdomyolysis, myopathy, myalgia, myasthenia, and creatine kinase elevation, have been reported in patients treated with finasteride.
- In some cases, these disorders were found to be reversible with discontinuation of finasteride therapy.

References

1. *Propecia (finasteride)* [product monograph]. Kirkland (QC): Merck Canada Inc.; 2018.
2. *Proscar (finasteride)* [product monograph]. Kirkland (QC): Merck Canada Inc.; 2018.

NOTICE OF MARKET AUTHORIZATION WITH CONDITIONS

A Notice of Compliance with Conditions (NOC/c) is a form of market authorization with conditions granted to a product on the basis of ***promising*** *evidence of clinical effectiveness following review of the submission by Health Canada. Communicating a NOC/c is intended to raise awareness on the details of the drug and the nature of authorization granted.*

Healthcare professionals are encouraged to report to Health Canada any adverse reactions suspected of being associated with marketed health products, including drugs authorized under the NOC/c policy.

The content of these notices reflects current information at the time of publication. Conditions associated with the NOC/c will remain until they have been fulfilled and authorized by Health Canada, in accordance with the NOC/c Policy. For the most up-to-date information, consult Health Canada's NOC database.

Lynparza (olaparib) tablet formulation: Authorization with conditions

Health Canada has issued a Notice of Compliance, under the Notice of Compliance with Conditions policy for Lynparza (olaparib) 100 mg and 150 mg oral tablets. Lynparza tablet formulation is indicated as monotherapy for the maintenance treatment of adult patients with platinum-sensitive relapsed BRCA wild type high-grade epithelial ovarian, fallopian tube or primary peritoneal cancer who are in response (complete or partial response) to platinum-based chemotherapy. Patients should be advised about the conditional market authorization for this indication.

For the complete prescribing information and information available for the patients/caregivers, please consult the Lynparza tablet Canadian product monograph. The product monograph can be accessed through Health Canada's Drug Product Database, the AstraZeneca website or by contacting AstraZeneca Canada Inc., at 1-800-668-6000. Contact the company for a copy of any references, attachments or enclosures.

Did you know?[1,2]

Lynparza (olaparib) is also available as a 50 mg capsule formulation. Lynparza capsules and tablets are NOT bioequivalent and are NOT interchangeable. There is a risk of confusion between Lynparza tablets and capsules that could lead to inadvertent use of the wrong formulation. To avoid medication errors, prescribers should specify the dosage form of capsules or tablets for Lynparza on each prescription. The two formulations must NOT be substituted on a milligram-to-milligram basis due to differences in dosing and bioavailability of each formulation. Refer to the relevant product monograph for specific dosing information.

Lynparza 50 mg capsules		Lynparza 150 mg tablets		Lynparza 100 mg tablets
Morning 8 capsules	Evening 8 capsules	Morning 2 tablets	Evening 2 tablets	Only to be used for tablet dose reductions
400 mg twice daily Total daily dosage: 800 mg		300 mg twice daily Total daily dosage: 600 mg		

References

1. *Lynparza (olaparib capsules)* [product monograph]. Mississauga (ON): AstraZeneca Canada Inc.; 2018.
2. *Lynparza (olaparib tablets)* [product monograph]. Mississauga (ON): AstraZeneca Canada Inc.; 2018.

HELPFUL LINKS

- MedEffect™ Canada
- Recalls and Safety Alerts Database
- Summary Safety Reviews
- New Safety Reviews
- Canada Vigilance Adverse Reaction Online Database
- Drug Product Database
- Medical Devices Active Licence Listing
- Licensed Natural Health Products Database
- The Drug and Health Product Register
- Drug Shortages Canada

Suggestions?

Your comments are important to us. Let us know what you think by reaching us at HC.infowatch-infovigilance.SC@canada.ca

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Adverse reactions (ARs) to health products are considered to be suspicions, as a definite causal association often cannot be determined. Spontaneous reports of ARs cannot be used to estimate the incidence of ARs because ARs remain underreported and patient exposure is unknown.

Due to time constraints relating to the production of this publication, information published may not reflect the most current information.

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